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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Members Representing Industry Interests on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for nonvoting industry representatives to serve on public advisory committees under the purview of the Center for Biologics Evaluation and Research (CBER).

DATES: Industry organizations interested in participating in the selection of a nonvoting member to represent industry for vacancies listed in this notice must send a letter to FDA by [*insert date 30 days after date of publication in the* **Federal Register**], stating their interest in one or more committees.

Concurrently, nomination materials for prospective candidates should be sent to FDA by [*insert date 30 days after date of publication in the* **Federal Register**]. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative.

ADDRESSES: All letters of interest and nominations should be sent to the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

FOR FURTHER INFORMATION CONTACT: Gail Dapolito, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20857–1448, 301–827–0314, e-mail: *dpolito@cber.fda.gov.*

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SUPPLEMENTARY INFORMATION: Section 120 of the FDA Modernization Act of (FDAMA) of 1997 (21 U.S.C. 355) requires that FDA advisory committees include representatives from the biologics manufacturing industries. The agency intends to add nonvoting industry representatives to all its advisory committees identified in section I of this document.

I. Functions

Advisory Committees Under the Purview of CBER

A. Allergenic Products Advisory Committee

The committee reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic diseases.

B. Blood Products Advisory Committee

The committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood and products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases.

C. Transmissible Spongiform Encephalopathies Advisory Committee

The committee reviews and evaluates available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health.

D. Vaccines and Related Biological Products Advisory Committee

The committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products

which are intended for use in the prevention, treatment, or diagnosis of human diseases.

II. Selection Procedure

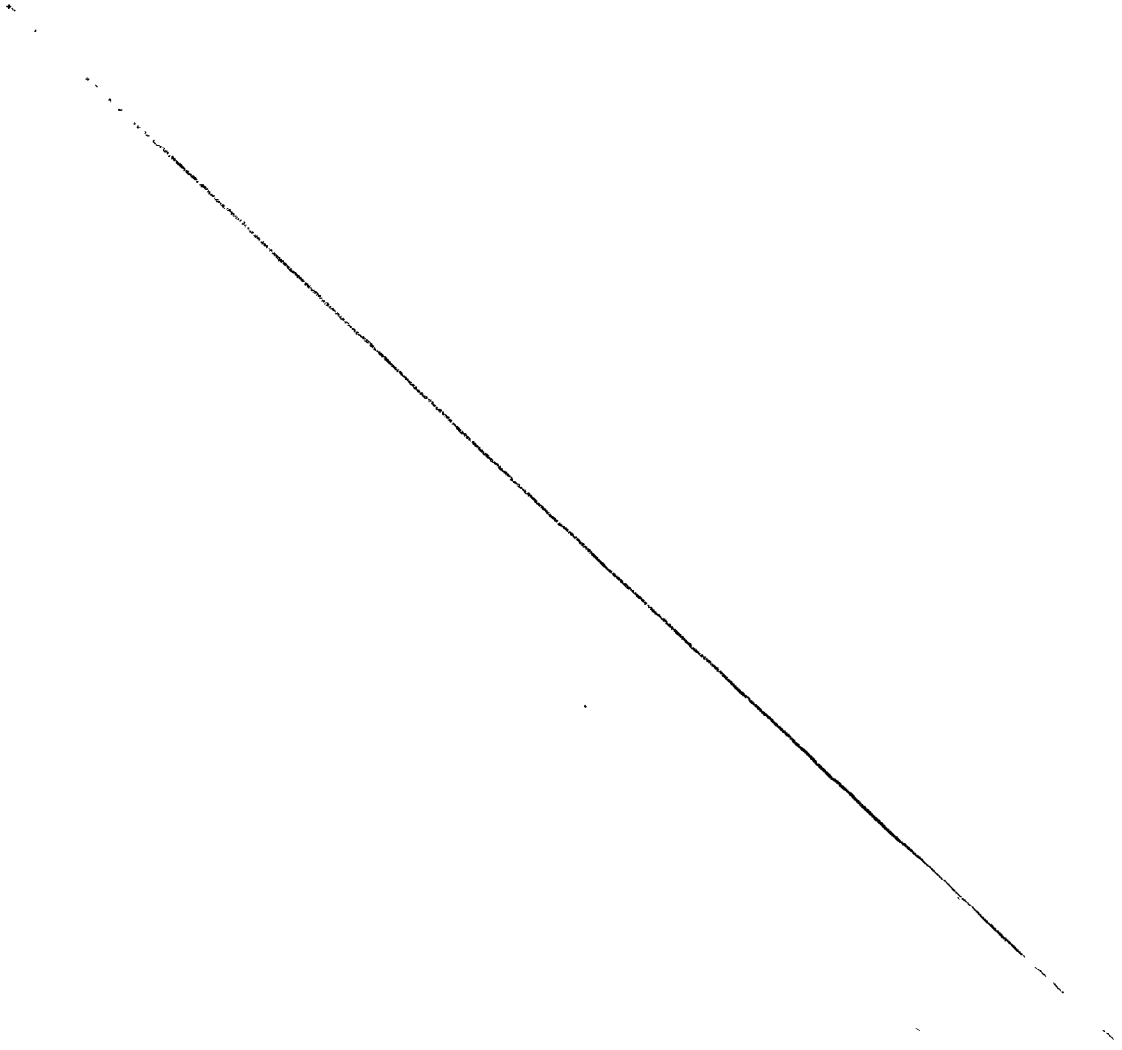
Any organization in the biologics manufacturing industry wishing to participate in the selection of a nonvoting member to represent industry on a particular advisory committee should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this notice. Persons who nominate themselves as industry representatives for a certain advisory committee will not participate in the selection process. It is, therefore, recommended that nominations be made by someone within an organization, trade association, or firm who is willing to participate in the selection process. Within the subsequent 30 days, FDA will send a letter to each organization and a list of all nominees along with their resumes. The letter will state that the interested organizations are responsible for conferring with one another to select a candidate, within 60 days after receiving the letter, to serve as the nonvoting member representing on a particular advisory committee. If no individual is selected within that 60 days, the Commissioner of Food and Drugs may select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may nominate themselves or an organization representing the biologics manufacturing industry may nominate one or more individuals to serve as nonvoting industry representatives. A current curriculum vitae (which includes the nominee's business address, telephone number, and e-mail address) and the name of the committee of interest should be sent to the FDA contact person. FDA will forward all nominations to the organizations that

have expressed interest in participating in the selection process for that committee.

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees. Therefore, the agency encourages nominations for appropriately qualified candidates from these groups.



This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: August 31, 2004.

August 31, 2004.

William K. Hubbard,
Associate Commissioner for Policy and Planning.

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